



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10502, CMS-10503, CMS-10504, CMS-10509, CMS-10418 and CMS-10157]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[Insert date 60 days after date of publication in the Federal Register]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be

submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10502 LTCH Quality Reporting Program: Program Evaluation

CMS-10503 Inpatient Rehabilitation Facilities (IRF) Quality Reporting Program (QRP): Program Evaluation

CMS-10504 Hospice Quality Reporting Program: Program Evaluation

CMS-10509 Prospective Evaluation of Evidence-Based Community Wellness and Prevention Programs

CMS-10418 Annual MLR and Rebate Calculation Report and MLR Rebate Notices

CMS-10157 HIPAA Eligibility Transaction System (HETS) Trading Partner Agreement (TPA)

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Long Term Care Hospital Quality Reporting Program:

Program Evaluation; Use: Section 3004(a) of the Affordable Care Act (ACA) mandated that we establish a quality reporting program for Long Term Care Hospitals (LTCHs). Specifically, section 3004(a) added section 1886(m)(5) to the Social Security Act (the Act) to establish a quality reporting program for LTCHs. This program requires that quality data be submitted by LTCH providers in a time, form and manner specified by the Secretary.

We are interested in exploring how LTCH providers are responding to the new quality reporting program (QRP) and its measures. We believe that it is important to understand early trends in outcomes, to make adjustments as needed to enhance the effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the QRP is useful and meaningful to providers. The methodology employed in the evaluation is the utilization of qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, we have decided that at this juncture it would be meaningful to use a rich, contextual approach to evaluation the process and success of the QRP initiative.

The decision to pursue this quantitative methodology in 2013, in which we learned that providers are anxious to have their voice heard, but that they did not feel comfortable expressing themselves fully in public open door forums. Providers desired some level of confidentiality, which this methodology affords. The intended use of the information collected is to help inform us about CMS providers' experiences related to the QRPs, such as program impact related to quality improvement, burden, process-related issues, and education. This will also inform future measurement development for the LTCH QRP, future steps related to data validation, as well as future monitoring and evaluation. General findings may be used to discuss our future efforts in the QRP. Form Number: CMS-10502 (OCN: 0938-NEW); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits and Not-for-profit organizations; Number of

Respondents: 30; Total Annual Responses: 30; Total Annual Hours: 71. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

2. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Inpatient Rehabilitation Facilities Quality Reporting Program: Program Evaluation; Use: Section 3004 of the Affordable Care Act (ACA) mandated that we establish a quality reporting program for Inpatient Rehabilitation Facilities (IRFs). Specifically, section 3004(a) added section 1886(j)(7) to the Social Security Act (“the Act”) to establish a quality reporting program (QRP) for IRFs. This program requires IRFs to submit quality data in a time, form and manner specified by the Secretary.

We are interested in exploring how IRF providers are responding to the new QRP and its measures. We believe that it is important to understand early trends in outcomes, to make adjustments as needed to enhance the effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the quality reporting program is useful and meaningful to the providers. The methodology employed in the evaluation is the utilization of qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, we have decided that at this juncture it would be meaningful to use a rich, contextual approach to evaluation the process and success of the QRP initiative. The decision to pursue this quantitative methodology in 2013, in which we learned that providers are anxious to have their voice heard, but that they did not feel comfortable expressing themselves fully in public open door forums. Providers desired some level of confidentiality, which this methodology affords.

The intended use of the information collected is to help inform CMS providers’ experiences related to the QRPs, such as program impact related to quality improvement, burden, process-related issues, and education. This will also inform future measurement development for

the IRF QRP, future steps related to data validation, as well as future monitoring and evaluation. General findings may be used to discuss our future efforts in the QRP. Form Number: CMS-10503 (OCN: 0938-NEW); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits and Not-for-profit organizations; Number of Respondents: 30; Total Annual Responses: 30; Total Annual Hours: 71. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

3. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Hospice Quality Reporting Program: Program Evaluation; Use: Section 3004(c) of the Affordable Care Act (ACA) mandated that we establish a quality reporting program (QRP) for hospices. Specifically, section 3004(c) added section 1814(i)(5) to the Social Security Act (the Act) to establish a quality reporting program for hospices. This program requires that quality data be submitted by hospices providers in a time, form and manner specified by the Secretary.

We are interested in exploring how hospice providers are responding to the new QRP and its measures. We believe that it is important to understand early trends in outcomes, to make adjustments as needed to enhance the effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the quality reporting program is useful and meaningful to the providers. The methodology employed in the evaluation is the utilization of qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, we have decided that at this juncture it would be meaningful to use a rich, contextual approach to evaluation the process and success of the QRP initiative. The decision to pursue this quantitative methodology in 2013, in which we learned that providers are anxious to have their voice heard,

but that they did not feel comfortable expressing themselves fully in public open door forums. Providers desired some level of confidentiality, which this methodology affords.

The intended use of the information collected is to help inform CMS providers' experiences related to the QRPs, such as program impact related to quality improvement, burden, process-related issues, and education. This will also inform future measurement development for the hospice QRP, future steps related to data validation, as well as future monitoring and evaluation. General findings may be used to discuss our future efforts in the QRP. Form Number: CMS-10504 (OCN: 0938-NEW); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits and Not-for-profit organizations; Number of Respondents: 30; Total Annual Responses: 30; Total Annual Hours: 71. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

4. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Prospective Evaluation of Evidence-Based Community Wellness and Prevention Programs; Use: Section 4202(b) of the Affordable Care Act (ACA) mandated that we conduct an evidence review and independent evaluation of wellness programs focusing on the following six intervention areas: chronic disease self-management, increasing physical activity, reducing obesity, improving diet and nutrition, reducing falls, and mental health management. In response to the ACA mandate, we adopted a three-phase approach to evaluate the impact of wellness programs on Medicare beneficiary health, utilization, and costs to determine whether broader Medicare beneficiary participation in wellness programs could lower future growth in Medicare spending. Phase I consisted of a comprehensive literature review and environmental scan to identify a list of wellness programs for further evaluation. Phase II involved a retrospective evaluation of 10 wellness programs in

the targeted intervention areas mentioned above. The purpose of the Phase II evaluation was to use Medicare claims data to assess the 10 wellness programs' impact on Medicare beneficiary outcomes including health service utilization and medical costs. The findings in Phase II were promising in that several wellness programs demonstrated the potential to save medical costs among participating beneficiaries.

Phase III of our evaluation, of which this work is the key component, aims to round out our understanding of how wellness programs affect Medicare beneficiaries and what cost saving opportunities exist for the Medicare program. This evaluation effort will 1) describe the overall distribution of readiness to engage with wellness programs in the Medicare population, 2) better adjust for selection biases of individual programs and interventions using beneficiary level survey data, 3) evaluate program impacts on health behaviors, self-reported health outcomes, and claims-based measures of utilization and costs, and 4) better describe program implementation, operations and cost in relation to the expected benefits. The results of these analyses will be used to inform wellness and prevention activities in the future.

To achieve the goals of this project, we will be conducting a nationally representative survey of Medicare beneficiaries to assess their readiness to participate in community-based wellness programs. National estimates of Medicare beneficiary demand for wellness services and benefits will be generated from this population-based readiness national survey. In addition, we will partner with evidence-based wellness programs for the purposes of enrolling an estimated 2,000 participants per program. Surveys of program participants will be conducted to assess program impacts on health and behavior. Form Number: CMS-10509 (OCN: 0938-NEW); Frequency: Semi-annually; Affected Public: Individuals and households; Number of

Respondents: 20,833; Total Annual Responses: 45,420; Total Annual Hours: 18,531. (For policy questions regarding this collection contact Benjamin Howell at 410-786-4942.)

5. Type of Information Collection Request: Revision of a currently approved collection;
Title of Information Collection: Annual MLR and Rebate Calculation Report and MLR Rebate Notices; Use: Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR Part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). An interim final rule (IFR) implementing the MLR was published on December 1, 2010 (75 FR 74865) and modified by technical corrections on December 30, 2010 (75 FR 82277), which added Part 158 to Title 45 of the Code of Federal Regulations. The IFR was effective January 1, 2011. A final rule regarding selected provisions of the IFR was published on December 7, 2011 (76 FR 76574) and an interim final rule regarding an issue not included in issuers' reporting obligations (disbursement of rebates by non-federal governmental plans) was also published December 7, 2011 (76 FR 76596). Both rules published on December 7, 2011 and were effective January 1, 2012. Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form we prescribed, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each

issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

Based upon HHS' experience in the MLR data collection and evaluation process, HHS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices. The 2013 MLR Reporting Form and instructions also reflect changes for the 2013 reporting year and beyond that are set forth in the March 2012 update to 45 CFR 158.120(d)(5) regarding aggregation of student health plans on a nationwide basis, similar to expatriate plans. The instructions also addresses recent applicability guidance issued by the Departments of Labor, Treasury and HHS concerning expatriate plan reporting prior to plan years ending before or on December 31, 2015. In 2014, it is expected that issuers will send fewer notices and rebate checks to policyholders and subscribers which will reduce burden on issuers. On the other hand, the requirement to report data on student health plans will increase burden for some issuers. It is estimated that there will be a net reduction in total information collection burden. Form Number: CMS-10418 (OCN: 0938-1164); Frequency: Annually; Affected Public: Private Sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 522; Number of Responses: 3,394; Total Annual Hours: 294,911. (For policy questions regarding this collection, contact Julie McCune at (301) 492-4196.)

6. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: HIPAA Eligibility Transaction System (HETS) Trading Partner Agreement (TPA); Use: The HIPAA Eligibility Transaction System (HETS) is intended to allow the release of eligibility data to Medicare providers, suppliers or their authorized billing agents for the purposes of preparing accurate Medicare claims, determining beneficiary liability or determining eligibility for specific services. Such information may not be

disclosed to anyone other than providers, suppliers or a beneficiary for whom a claim has been filed. Form Number: CMS-10157(OCN: 0938-0960); Frequency: Yearly; Affected Public: Private sector - Business or other for-profit and Not-for-profit institutions; Number of Respondents: 1,000; Total Annual Responses: 1,000; Total Annual Hours: 125. (For policy questions regarding this collection contact Ada Sanchez at 410-786-9466.)

Dated: November 19, 2013

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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